

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/891,983	SHAH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachariah Lucas	1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the submission of October 5, 2005.
2. ☒ The allowed claim(s) is/are claims 8 and 9.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |                                                                                                                                         |                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                             | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                    | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>10/5/05</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                              | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|                                                                                                                                         | 9. <input type="checkbox"/> Other _____.                                               |

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### DETAILED ACTION

1. Currently, claims 8 and 9 are pending in the application. In the prior action, mailed on July 6, 2005, claims 8 and 9 were pending and rejected. The Applicant submitted a Response on October 5, 2005 containing arguments and submissions in traversal of the rejection.
2. For the reasons indicated below, claims 8 and 9 are allowed.

#### *Oath/Declaration*

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It was not executed in accordance with either 37 CFR 1.66 or 1.68. I.e., there is no clear signature on the Oath/Declaration submitted in the present application.

Applicant is requested to submit a new executed copy of the Oath/Declaration.

4. Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth above. The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" (PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the "Notice of Allowance" (PTOL-85) and the application number in the upper right hand corner.

***Information Disclosure Statement***

5. The information disclosure statement (IDS) submitted on October 5, 2005, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

6. It is noted that the Aoyagi et al reference cited in the IDS has been crossed out. This reference was previously made of record and considered in the IDS of January 2002.

7. It is further noted that the IDS identifies U.S. Patent 6,486,479 as issued in June 1996 to ITO et al. It appears that the Applicant intended to refer to U.S. Patent 5,486,479, which patent has also been considered and cited in the attached form 892.

***Claim Rejections - 35 USC § 112***

8. **(Prior Rejection-Withdrawn)** Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The antibodies C11-14 and C11-10 are required to practice the claimed invention because they are needed to perform the claimed method. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. In traversal of the rejection, the Applicant has submitted a statement by the director of the National Institute of Advanced Industrial Science and Technology (the depository in which the cells producing the antibodies

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C11-14 and C11-10 have been deposited) stating that the antibodies are available under the conditions of the Budapest Treaty. The Applicant asserts that this submission provides evidence of the public availability of the antibodies used in the claims. This argument is found persuasive. The rejection is therefore withdrawn.

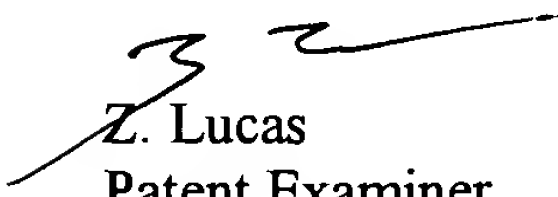
### *Conclusion*


9. Claims 8 and 9 are allowed for the reasons indicated in the prior actions. I.e., as argued by the Applicant in the Response filed on May 24, 2004 (received by Office May 28, 2004), the method of claims 8 and 9 show unexpected results over the prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas  
Patent Examiner

  
JAMES HOUSEL 1/5/06  
SUPERVISORY PATENT EXAMINER  
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